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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

16 JUN 2005


(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P145 WO 01	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/40520	International filing date (day/month/year) 19 December 2003 (19.12.2003)	Priority date (day/month/year) 20 December 2002 (20.12.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): G01N 31/00 and US Cl.: 702/22		
Applicant DAKOCYTOMATION DENMARK A/S		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 15 July 2004 (15.07.2004)	Date of completion of this report 27 April 2005 (27.04.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Marc S. Hoff  Telephone No. 703-305-0976

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I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-14 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the claims:
pages 15-19 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the drawings:
pages 1-4 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 4-32

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4-32 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 4-32 are in improper multiple dependent form and do not comply with PCT Rule 6.4(a).

☐ the claims, or said claims Nos: _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-3, 33-39</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>34, 36, 37</u>	YES
	Claims <u>1-3, 33, 35, 38, 39</u>	NO
Industrial Applicability (IA)	Claims <u>1-3, 33-39</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

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VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 16 and 38 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof:

In claim 16, line 2 of the claim, delete "exchanging", and insert --exchange--.

In claim 38, line 1 of the claim, delete "disfectants", and insert -disinfectants-.

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claim 38 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 38 is indefinite for the following reason(s): The claim recites limitations for adding other compounds. It is unclear what compounds are included in other compounds.

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PCT/US03/40520**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Claims 1-3 and 33 lack an inventive step under PCT Article 33(3) as being obvious over Coville et al. (US Patent No. 4,695,430) in view of Modlin et al. (US Patent Application Publication 2001/0006417). With regard to a housing, as shown in claims 1 and 33, Coville et al. teach a housing (col. 6, lines 40-44). With regard to a sample processing section in a housing or interior space with a sample carrier member, as shown in claims 1 and 33, Coville et al. teach an analyzer with a conveyer for analyzing blood samples (col. 3, line 27 - col. 5, line 25; col. 6, line 50 - col. 7, line 54). With regard to a climate control device and a sensor providing feedback to the climate control means and ventilating means, as shown in claims 1 and 33, Coville et al. teach controlling the temperature using a temperature sensor, heating means, and a cold modules (col. 7, lines 1-13; col. 13, lines 56-60).

Coville et al. do not teach a cover protecting the sample and defining the interior space between the housing and the cover, as shown in claims 1 and 33. Modlin et al. teach a cover for enclosing an interior sample space (pars. 53-55; Fig. 7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analytical apparatus, as taught by Coville et al., to include a cover for the housing, as taught by Modlin et al., because then access to the sample space would have been facilitated while allowing the sample to be sealed during testing.

With regard to sensing temperature, as shown in claim 2 and internal sensors, Coville et al. teach sensing internal temperature (col. 15, lines 56-60).

Claims 35 and 39 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Shofner et al. (US Patent Application Publication 2002/0178547). Coville et al. and Modlin et al. teach all the limitations of claim 33 upon which claims 35 and 39 depend. Coville et al. and Modlin et al. do not teach spraying water droplets or having a water surface, as shown in claims 35 and 39. Shofner et al. teach using aerosol water (par. 28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analytical apparatus combination, as taught by Coville et al. and Modlin et al., to include using aerosol water, as taught by Shofner et al., because then humidity would have been controlled.

Claim 38 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Virtanen (US Patent Application Publication 2001/0037072). Coville et al. and Modlin et al. teach all the limitations of claim 33 upon which claim 38 depends. Coville et al. and Modlin et al. do not teach adding disinfectants, UV protectants or other compounds to the inlet air, as shown in claim 38. Virtanen teach adding a disinfectant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer apparatus combination, as taught by Coville et al. and Modlin et al., to include adding disinfectant, because then pathogens would have been killed (Virtanen, par. 34).

Claims 34, 36 and 37 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of automatically processing one or more biological samples that includes applying reagent in a processing apparatus in a housing with a cover enclosing the samples and ventilating the interior space of the apparatus and drawing inlet air through a humid filter to ensure high and uniform humidity in the chamber or drawing recycled air through filters to remove fumes and filters to adjust the humidity or

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(To be used when the space in any of the preceding boxes is not sufficient)

controlling the humidity to never e below a predetermined level.

Claims 1-3 and 33-39 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----